

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

256299
DP Barcode: 262299
Page: 1 of 44

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: April 14, 2004

SUBJECT: **Propiconazole** Risk Assessments for the Section 18 Request for Control of Soybean Rust

PC Code: 122101

DP Barcode: ~~262299~~
256299REVIEWER: J. R. Tomerlin, Ph.D., Plant Pathologist
Fungicides Branch/Registration Division (7505C)THROUGH: Richard Loranger, Branch Senior Scientist
Registration Action Branch 1/Health Effects Division (7509C)TO: Andrew Ertman/Section 18 Team
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)**Executive Summary**

Assessments of human exposures and risks were conducted for acute and chronic dietary risk, exposure and risk to propiconazole residues in water, residential exposure and risk, aggregate risk, and exposure and risk to workers. The assessments were performed to support a Section 18 request from the States of Minnesota (04MN01) and South Dakota (04SD01) for use of propiconazole on soybeans to control soybean rust, caused by *Phakopsora pachyrhizi*. The residue of concern is propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid, expressed as parent compound..

For purposes of this Section 18 petition, only parent propiconazole is being considered. The Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid. These three compounds are metabolites to most of the triazole-containing fungicides. When suitable information about the toxicity of these compounds

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Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 2 of 44

is available, the Agency may revisit the risk issues.

Acute Dietary Exposure Results and Characterization

The results of the acute dietary exposure analysis are reported in Table 3. For acute dietary risk assessments, the Agency is concerned when dietary risk exceeds 100% of the aPAD. Given that estimated exposure at the 95th percentile is less than 5% of the aPAD for all population groups, acute dietary risk is not an issue for the Section 18 request for the use of propiconazole on soybean.

Chronic Dietary Exposure Results and Characterization

The results of the chronic dietary exposure analysis are reported in the summary Table 3. For chronic dietary risk assessments, the Agency is concerned when dietary risk exceeds 100% of the cPAD. Given that mean estimated exposure is no more than 6% of the cPAD for all population groups, chronic dietary risk is not an issue for the Section 18 request for the use of propiconazole on soybean. Propiconazole has been classified as a possible human carcinogen, non-quantifiable. Consequently, the standard chronic dietary exposure analysis and risk assessment using the cPAD serves as the assessment for cancer. Since carcinogenic risk for propiconazole is addressed with the cPAD, cancer risk from the proposed use on soybeans is not expected to be of concern.

Risk from Residues in Water

The Agency used the First Index Reservoir Screening Tool (FIRST) to calculate estimated environmental concentrations¹ (EECs) in surface water and the Screening Concentration in Ground Water (SCI-GROW) to calculate propiconazole EECs in ground water. Based on the FIRST model, the estimated environmental concentrations (EECs) of propiconazole in surface water are 264 ppb and 80 ppb for acute and chronic exposures, respectively. The EEC for both acute and chronic exposures is estimated as 1.5 ppb for ground water using the SCI-GROW model.

The assessments assumed use patterns of: 8 applications per year, 0.885 lb ai/A per application, and a 14-day interval. The proposed use pattern for propiconazole under the Section 18 request

¹"Section 18 Ecological Risk and Drinking Water Exposure Assessment for the Control of Soybean Rust Using: Propiconazole (122101); DP 296314; Boscolid (128008): DP 296315; Pyraclostrobin (099100); DP 296317; Trifloxystrobin (129112); DP 296318; Myclobutanil (128857); DP 296319; Tebuconazole (128997): DP 296320." Memorandum From S. Abel, A Al-Mudallah, K. Costello, and T. Nguyen, March 30, 2004.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 3 of 44

is no more than 2 applications of 0.225 lb ai/A; the requested PHI is 28 days. Therefore, the assumptions under which the water EEC values were calculated lead to an overestimate of the potential residue concentration in water from the use of propiconazole on soybeans and the Agency does not expect that propiconazole residues in drinking water will exceed the levels estimated by the FIRST and SCI-GROW models.

Residential Exposure and Risk

Propiconazole is a fungicide that can be used to control turfgrass diseases on residential lawns, sod farms and golf courses. There is potential, therefore, for dermal exposures to propiconazole residues on treated turf. Exposure was evaluated and MOEs ranged from 13000 to 60000 for adults and from 30000 to 150000 for children. Exposure and MOE varied according to the location of the study that generated the data used for the assessment, with the lowest MOE values being calculated from data obtained in a California study. The MOE for oral ingestion by children was 3000. The assessment is conservative because it assumes reentry immediately after the application of propiconazole at the highest recommended rate of 1.79 pounds ai per acre. A conservative estimate of acres treated with propiconazole is 18,000 based on the assumption that all of the propiconazole available for the consumer market is applied to lawns. There are approximately 30 million acres of lawns in the United States according to Kline and Company². Therefore, less than 0.1 percent of the lawns are likely to be treated. It is unlikely that the maximum application rate would be used in a hot dry climate. Furthermore, the trial was conducted on three-month old stand of turf, too new for most established lawns in California. Based on these facts, plus the fact that the majority of use is likely to be in the Midwest and northeastern United States, the exposure scenario represented by the California data is assumed to be worst case and assumed to be an unlikely event. Nonetheless, aggregate exposure was estimated using the results from the California trial and is considered to be an overestimate of potential aggregate exposure and risk.

Occupational Exposure and Risk

Based on the proposed use patterns in soybeans, occupational handlers are expected to have dermal and inhalation exposures. The lowest estimated MOE is 220 (combined dermal and inhalation) for mixer/loaders. Note that the combined MOE of 220 is achieved for workers without gloves. With gloves, the combined MOE for dermal and inhalation exposures for mixer/loaders is 4700. At this time, the Agency sees no reason to revise the current label instruction to wear gloves when mixing and loading propiconazole; however, wearing gloves is good industrial hygiene practice.

²Email from J. Evans (OPP/HED/CEB) to J. R. Tomerlin (OPP/RD/FB), 4/1/04.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 4 of 44

Because of the high interest in soybean rust and the need to scout fields to confirm its presence, the Agency conducted an assessment of post-application exposures for scouting activities. Post-application MOEs are 30000 for females and 90000 for the general population. Since the Agency's level of concern for propiconazole is for MOEs less than 100, potential risk for occupational post-application exposures is well below the Agency's level of concern.

Aggregate Exposure and Risk

Aggregate exposure and risk assessments were performed for acute (food + drinking water), chronic (food + drinking water), and short-term (food + drinking water + residential) aggregate exposure. Acute aggregate risk estimates for adults and children do not exceed the Agency's level of concern. The drinking water levels of comparison (DWLOCs) are substantially greater than the acute drinking water EECs. The acute DWLOC range from 2900 to 10000 ppb. Compared to EFED's surface and ground water EECs, the DWLOC is considerably greater and therefore, acute aggregate risk is not expected to exceed the Agency's level of concern. Short-term exposure and risk for infants has a calculated DWLOC of 2600, which is greater than the EECs calculated by EFED and is not of concern to the Agency. The calculated chronic DWLOCs for chronic exposure to propiconazole in drinking water range from 940 to 3400 µg/L (ppb). EECs generated by EFED are less than the Agency's calculated chronic DWLOCs. Therefore, the chronic aggregate risk associated with the proposed use of propiconazole is not expected to exceed the Agency's level of concern for the general U.S. population or any population subgroups. As shown in this summary, the Agency does not have any concerns about aggregate exposure and risk from the use of propiconazole on soybeans to control soybean rust.

The aggregate exposure/risk assessments (acute, short-term, chronic and cancer) are considered conservative estimates, that are not expected to underestimate risks, and support time-limited tolerances of 0.5 ppm in soybeans, 8 ppm in soybean forage, and 25 ppm in soybean hay.

I. Introduction

The States of Minnesota (04MN01) and South Dakota (04SD01) have petitioned the Agency requesting an Emergency Exemption for propiconazole to control soybean rust under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In conjunction with that petition, the petitioners have requested the establishment of temporary tolerances for residues of propiconazole on soybeans.

Although *Phakopsora pachyrhizi*, the soybean rust pathogen, has not yet been identified in the continental United States, it has been detected in South America. As a designated biosecurity threat, it is important that control measures be available if soybean rust is identified in the United States. Under the proposed use, soybeans could be treated upon the official confirmed identification of soybean rust in the United States.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 5 of 44

II. Residue Information

Propiconazole Registrations:

Tolerances listed in 40 CFR § 180.434 were used for all assessments of dietary risk, both acute and chronic. The residue of concern is parent propiconazole and metabolites containing the 2,4-dichlorophenyl moiety³, as concluded by the Metabolism Assessment Review Committee (MARC). The MARC further stated that "... issues concerning metabolites of propiconazole containing only the triazole ring (free triazole and conjugates of free triazole) are expected to be addressed through separate deliberations... The Committee believes these issues may be handled separately without conflict of outcomes."

The existing tolerances are shown in Table 1.

Table 1: Tolerances for Propiconazole (40 CFR § 180.434)	
Commodity	Tolerance (ppm)
Crops	
Banana	0.2
Barley, grain	0.1
Celery	5.0
Corn, field, grain	0.1
Corn, sweet, kernel plus cob with husks removed	0.1
Cranberry - expires 12/31/05	1.0
Dry bean - expires 12/31/05	0.5
Egg	0.1
Fruit, stone, group 12	1.0
Milk	0.05
Mint, tops (leaves and stems) - regional registration	0.3
Mushroom	0.1
Oat, grain	0.1

³Propiconazole (122101): Results of the HED Metabolism Assessment Review Committee (MARC) Meetings Held on 19-December-2001 and 08-January-2002, TXR# 0050349, April 4, 2002.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 6 of 44

Table 1: Tolerances for Propiconazole (40 CFR § 180.434)	
Commodity	Tolerance (ppm)
Peanut	0.2
Pecans	0.1
Pineapple	0.1
Plum, prune, fresh	1.0
Rice, grain	0.1
Rye, grain	0.1
Sorghum, grain - expires 6/30/05	0.2
Wheat, grain	0.1
Wild rice - regional registration	0.5
Edible Animal Tissues	
Fat of cattle, goat, hog, horse and sheep	0.1
Kidney and liver of cattle, goat, hog, horse and sheep	2.0
Meat byproducts (except kidney and liver) of cattle, goat, hog, horse and sheep	0.1
Meat of cattle, goat, hog, horse and sheep	0.1
Kidney and liver of poultry	0.2
Meat byproducts (except kidney and liver) of poultry	0.1
Meat of poultry	0.1
NOTE: Tolerances in animal feedstuffs (e.g., barley straw) are not included in this tolerance summary	

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 7 of 44

Propiconazole on Soybean:

Data from residue field trials were available for estimating residues in soybean⁴. Plots were treated with two applications of 75 g a.i./A, 150 g a.i./A or 225 g a.i./A. The Section 18 request from Minnesota and South Dakota requests up to two applications of 1.8 oz (51 g) to 3.6 oz (102 g) a.i. per acre⁵. Regarding the potential impact of the soybean use on secondary residues in edible animal tissues, the Agency previously determined that residues on soybeans would not change tolerances in livestock from existing levels⁶. Soybean residue data from the 75 g a.i./A trial (2 applications) support tolerances of:

Soybean	0.5 ppm
Soybean forage	8 ppm
Soybean hay	25 ppm

Note that the Section 18 requests includes a 28-day PHI. The available field trials applied propiconazole at growth stage R3 (beginning pod), with a second application approximately 21 days later at growth stage R5 (pod fill). The resulting PHIs from this treatment regime ranged from 46 to 99 days after the last treatment. Therefore, the use directions should specify the soybean growth stages - R3 and R5 - at which propiconazole may be applied.

Therefore, the residues used in the Section 18 risk assessment were tolerances as specified in 40 CFR § 180.434 (summarized in Table 1) and 0.5 ppm in soybeans. Both the acute and chronic risk assessments assumed tolerance level residues as described above and 100% crop treated. The residue file for the assessments is shown in Attachment 1. The standard enforcement

⁴Smith, J. W., 1994, "Magnitude of Residues of Propiconazole (Tilt®) in or on Soybean Beans, Fodder, Forage, and Hay Following Application of Tilt® 3.6E. Ciba-Geigy Report ABR-94013. MRID# 43386502.

⁵The original Section 18 request was for 1.8 oz a.i./A. However, a revised application rate was received by the Agency on January 30, 2004 requesting up to two applications at rates ranging from 1.8 to 3.6 oz a.i./A.

⁶"PP5F04424 & ID#000100-00618 CGA-64250 Technical: Propiconazole in/on Dry Beans and Soybeans. Evaluation of Residue Data and Analytical Methodology. CBTS #s 14859 & 14860; DP Barcode #s D210266 & D210295; Case #s 286012 & 037683; MRID #s 433865-00, 433865-01, & 433865-02." Memorandum from M. I. Rodriguez to D. L. McCall and S. Robbins, March 5, 1997.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 8 of 44

analytical method⁷ is capable of detecting propiconazole residues in soybeans.

III. DEEM-FCID™ Program and Consumption Information

Propiconazole acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, the Agency concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the special FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk

⁷ Lin, K. (1997) Determination of Total Residues of Propiconazole in Crops as 2,4-Dichlorobenzoic Acid Methyl Ester by Capillary Gas Chromatography: Lab Project Number: AG-626; 571-97: 411925. Unpublished study prepared by Novartis Crop Protection, Inc. 45 p. [OPPTS 860.1340, MRID #44411201]

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 9 of 44

exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/99).

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with Agency policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

IV. Toxicological Information

The HIARC met on 9 December 2003 to determine endpoint selection for propiconazole. At this meeting, the HIARC also reassessed FQPA requirements in response to questions posed by the Natural Resources Defense Council (NRDC). No new data have been reviewed and no changes were made to the toxicology endpoints previously selected for propiconazole (with the exception of the FQPA safety factor applied). The HED HIARC re-evaluated the short-term dermal endpoint to address the appropriate populations of concern; the report of this meeting revises the previous HIARC report dated March 26, 2003 (HED DOC. NO. 0051703). The 3rd HIARC for propiconazole confirmed the conclusions of the HED Carcinogenicity Peer Review Committee (CPRC) of, April 15, 1992 (HED Doc. No. 009771): propiconazole was classified as a Group C - possible human carcinogen and recommended that for the purpose of risk characterization the reference Dose (RfD) approach should be used for quantification of human risk. However, it should be noted that present policy is to refer to such chemicals as a "possible human carcinogen, non-quantifiable."

The toxicity endpoints pertinent for human risk assessment are summarized in Table 2.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 10 of 44

**Table 2. Summary of Toxicological Doses and Endpoints for Propiconazole
for Use in Human Health Risk Assessment**

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor	Study and Toxicological Effects
Acute Dietary (Females 13-50)	NOAEL = 30 mg/kg/day UF = 300 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1X aPAD = acute RfD = 0.1 mg/kg/day	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity manifested by increased incidence of rudimentary ribs, cleft palate malformations (0.3%) unossified sternebrae, as well as increased incidence of shortened and absent renal papillae.
Acute Dietary (General Population)	NOAEL = 90 mg/kg/day UF = 300 Acute RfD = 0.3 mg/kg/day	FQPA SF = 1X aPAD = acute RfD = 0.3 mg/kg/day	Developmental Toxicity Study - Rats. LOAEL = 300 mg/kg/day based on developmental toxicity manifested by severe maternal toxicity: ataxia, coma, lethargy, prostration, audible and labored respiration, salivation and lacrimation
Chronic Dietary (All populations)	NOAEL = 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD = 0.1 mg/kg/day	24 Month Oncogenicity Study - Mice. LOAEL = 50 mg/kg/day based on liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/ swellings/nodular areas mainly)

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 11 of 44

**Table 2. Summary of Toxicological Doses and Endpoints for Propiconazole
for Use in Human Health Risk Assessment**

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor	Study and Toxicological Effects
Short Term (1-30 days) Incidental Oral	Maternal NOAEL = 90 mg ai/kg/day	Residential MOE = 300 Occupational = NA	Developmental Toxicity Study - Rats. LOAEL = 360 mg/kg/day based on severe clinical signs
Intermediate Term (1-6 months) Incidental Oral	NOAEL = 10 mg ai/kg/day	Residential MOE = 100 Occupational = NA	24 Month Oncogenicity Study - Mice. LOAEL = 50 mg/kg/day based on liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas mainly))
Short Term (1-30 days) Dermal (Females 13-50 years old)	Oral Developmental NOAEL = 30 mg ai/kg/day Dermal absorption rate ¹ = 1%	Residential MOE = 300 Occupational MOE = 100	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity: increased incidence of rudimentary ribs, unossified sternebrae, and shortened and absent renal papillae.
Short Term (1-30 days) Dermal (General Populations, including infants and children)	Oral Maternal NOAEL = 90 mg ai/kg/day Dermal absorption rate ¹ = 1%)	Residential MOE = 300 Occupational MOE = 100	Developmental Toxicity Study - Rats. LOAEL = 300 mg/kg/day based on severe maternal clinical toxicity (ataxia, coma, lethargy, prostration, audible and labored respiration, salivation and lacrimation)

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 12 of 44

**Table 2. Summary of Toxicological Doses and Endpoints for Propiconazole
for Use in Human Health Risk Assessment**

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor	Study and Toxicological Effects
Intermediate Term (1-6 months) and Long Term Dermal (> 6 months)	Oral NOAEL = 10 mg ai/kg/day (Dermal absorption rate ¹ = 1%)	Residential MOE = 100 Occupational MOE = 100	24 Month Oncogenicity Study - Mice. LOAEL = 50 mg/kg/day based on liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas mainly)
Short Term (1-30 Days) Inhalation	Oral Developmental NOAEL = 30 mg/kg/day (Inhalation absorption rate = 100%)	Residential MOE = 300 Occupational MOE = 100	Developmental Toxicity Study - Rats. LOAEL = 90 mg/kg/day based on developmental toxicity manifested by increased incidence of rudimentary ribs, unossified sternbrae, as well as increased incidence of shortened and absent renal papillae.
Intermediate Term (1-6 months) and Long Term Inhalation (> 6 months)	Oral NOAEL = 10 mg/kg/day (Inhalation absorption rate = 100%)	Residential MOE = 100 Occupational MOE = 100	24 Month Oncogenicity Study - Mice. LOAEL = 50 mg/kg/day based on liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas mainly)
Cancer	Group C - possible human carcinogen, non-quantifiable		
1 Per email from J. Evans (OPP/HED/CEB) to J. R. Tomerlin (OPP/RD/FB), 4/5/04.			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 13 of 44

V. Results/Discussion

Results of Acute Dietary Exposure Analysis

The acute assessment was a Tier I assessment using tolerances as listed in 40 CFR § 180.434 and the DEEM-FCID™ program. One hundred percent crop treated was assumed for all commodities. Default processing factors from DEEM were used for processed commodities when available. The residue file used for both the acute and chronic assessments is shown in Attachment 1. The resulting exposure estimates were compared to the acute population adjusted dose (aPAD) for propiconazole of 0.1 mg/kg bw/day for women aged 13 to 49 and 0.3 mg/kg bw/day for the general US population⁸. This assessment should be considered conservative and unrefined in that tolerance level residues were used for all food commodities and there was no adjustment made for the percent of the crop that is treated.

The 95th percentile of the acute exposure distribution is the appropriate point at which to evaluate risk in a Tier I assessment. The results of the acute exposure analysis show that for the overall U.S. population, estimated exposure at the 95th percentile of the exposure distribution is 0.005540 mg/kg bw/day, equivalent to 2% of the aPAD. The most highly exposed population group is All Infants <1 year old, with an estimated exposure at the 95th percentile of 0.013057 mg/kg bw/day, equivalent to 4% of the aPAD. The estimated 95th percentile exposure for females 13-49 years of age is 0.003854 mg/kg bw/day, equivalent to 4% of the aPAD. The smaller exposure estimate for females results in a larger percentage of the aPAD because the appropriate aPAD for females is 3-fold lower than that for the general population. Acute exposure is summarized in Table 3, and the complete exposure distributions are provided in Attachment 2.

Results of Chronic Dietary Exposure Analysis

The chronic dietary exposure assessment also used tolerance level residues as listed in 40 CFR § 180.434 and the chronic analysis module of the DEEM-FCID™ software. As with the acute assessment, default DEEM processing factors were used, and no adjustments were made for percent crop treated.

Estimated exposure for the total U.S. Population was 0.001984 mg/kg bw/day, equivalent to 2% of the cPAD of 0.1 mg/kg bw/day. The two most highly exposed population sub-groups, children 1-2 and children 3-5, had estimated exposures of 0.005877 and 0.004615 mg/kg bw/day, respectively. These exposures were equivalent to 6% and 5% of the cPAD. Chronic exposure risk is shown in Table 3, and results for all population sub-groups are shown in Attachment 3.

⁸“PROPICONAZOLE - 3rd Report of the Hazard Identification Assessment Review Committee,” December 17, 2003, TXR NO. 0052277

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 14 of 44

Propiconazole has been classified as a possible human carcinogen, non-quantifiable. As such, the cancer risk assessment for propiconazole is evaluated using the standard cPAD; the use of propiconazole on soybeans is not expected to result in unacceptable cancer risks.

Table 3. Summary of Dietary Exposure and Risk for Propiconazole				
Population Subgroup	Acute Dietary (95 th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.005540	2	0.001984	2
All Infants (< 1 year old)	0.013057	4	0.003736	4
Children 1-2 years old	0.012848	4	0.005877	6
Children 3-5 years old	0.010216	4	0.004615	5
Children 6-12 years old	0.006745	2	0.003007	3
Youth 13-19 years old	0.003983	1	0.001728	2
Adults 20-49 years old	0.003809	1	0.001478	2
Adults 50+ years old	0.004062	1	0.001494	2
Females 13-49 years old	0.003854	4	0.001437	1

Water Exposure and Risk

There are no health advisory levels or Maximum Contaminant Levels established for residues of propiconazole in drinking water. The Agency used the First Index Reservoir Screening Tool

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 15 of 44

(FIRST) and the Screening Concentration in Ground Water (SCI-GROW) screening models to determine the Estimated Environmental Concentrations (EECs) of propiconazole in surface and ground water, respectively. Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of propiconazole for acute exposures are 264 parts per billion (ppb) for surface water and 1.5 ppb for ground water. The EECs for chronic exposures are 80 ppb for surface water and 1.5 ppb for ground water.

A drinking water level of comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. The Agency uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water.

Residential Risks

Propiconazole is a fungicide used to control turfgrass diseases on residential lawns, sod farms and golf courses. Label directions indicate that spray applications ranging from ~0.25 to 1.79 pounds active ingredient (a.i.) per acre are made to these sites as part of a preventative disease control program. Syngenta has submitted a report: Determination of Transferable Turf Residues on Turf Treated with Banner MAXX (propiconazole) to support the registration of propiconazole for use on turf and for use in residential risk assessments [MRID 452886-01]. In the study, propiconazole was applied to turfgrass plots located in three geographic locations (Indiana, Pennsylvania and California) at the maximum rate of 1.79 pounds ai. Turf transferable residues (TTR) were collected following the applications at intervals of 0, 4, 8 and 24 hours after application and 2, 3, 5, 8, 10, 14, and 21 days after application using the modified California roller technique. The respective half lives of propiconazole measured in Indiana, Pennsylvania and California are 2.2 days, 1.9 days and 1.3 days.

Note that the residential risk assessment was provided by J. Evans of OPP/HED/CEB, as previously cited (page 3).

Dermal Exposure and Risk

Syngenta selected the geographic locations of Indiana and Pennsylvania because these areas are representative of the product use profile of propiconazole; the midwest and northeastern areas of the United States. California was selected as a worst case area represented by hot dry conditions that make turf disease pressure less likely than the midwest and northeastern sites. The turfgrass grown in the study sites of Indiana and Pennsylvania was well established ranging 3 to 7 years while the site in California was characterized as being established for approximately 3 months.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 16 of 44

The lack of thatch in the turfgrass at the California site may have impacted the TTR data at that site. The following table presents the residue measurements for the three sites at "time zero" defined as: as soon as sprays have dried. In the table, the percent of the application rate available as transferable residue (transfer efficiency) at time zero is also presented.

Table 4. Time "Zero" Residue Measurements on Turf		
Study Location	Time Zero Residue ($\mu\text{g}/\text{cm}^2$)	Percent of Application Rate*
Indiana	0.018	0.089
Pennsylvania	0.050	0.25
California	0.108	0.53
Application rate in study: $1.79 \text{ lb ai/acre} = 20.06 \mu\text{g}/\text{cm}^2 \div \text{Time Zero TTR } (\mu\text{g}/\text{cm}^2)$		

There are various techniques used to measure turf transferable residues (TTR) all of which have varying transfer efficiencies. The transfer efficiency of the modified California roller is less than 1 percent. This value is below the lower limit of compatibility with Agency transfer coefficients for chemicals applied to turfgrass, as delineated in Exposure SAC policy 12. An appropriate study for use with TTR data generated using the modified California roller is presented in the Outdoor Residential Exposure Task Force Study entitled: The ORETF Algorithm for Defining the Relationship of Transferable Turf Residues to Post-Application Dermal Exposure [MRID461905-01]. In that study, post application exposure to a turfgrass pesticide was measured using passive dosimetry and TTR data generated using the modified California roller. The efficiency of the TTR measurement in the ORETF study was 0.5% making it appropriate for use with the data presented in the above table. A preliminary review of these data suggest a transfer coefficient of $70,000 \text{ cm}^2/\text{hour}$ representing an adult wearing short pants, a short sleeved shirt and enclosed footwear. This value is based on measurements of volunteers performing post application activities on turf (e.g., crawling, touch football, soccer) as soon as the pesticide dried. This transfer coefficient will be used with the time zero residue data presented above.

The Agency considered two recent dermal absorption studies supplied by the registrant (Study #044AM01 and study #044AM02). In study 044AM01, the *in vivo* dermal absorption in rats was approximately 12%, 17%, and 7% at the low, medium and high doses, respectively. In an *in vitro* study (Study #044AM02), the factor of difference ($\text{dermal absorption}_{\text{RAT}}/\text{dermal absorption}_{\text{HUMAN}}$) was 9.5, 18.6 and 10.9 at the low, medium, and high doses, respectively. The highest estimated dermal absorption coefficient was approximately 1% at the low dose. Thus, 1% dermal absorption was assumed in the dermal risk calculations. Note that information about the dermal absorption coefficient was provided by J. Evans of OPP/HED/CEB, as cited

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 17 of 44

previously (Footnote to Table 2).

Post application dermal exposure to turfgrass chemicals is estimated using the following algorithm:

$$\frac{\text{TTR } (\mu\text{g}/\text{cm}^2) * \text{Trans Co. } (\text{cm}^2/\text{hour}) * \text{hours on turf} * \text{Dermal absorption} * 1 \text{ mg}/1000 \text{ ug}}{\text{Body weight (kg)}}$$

For adults, a body weight of 60 kg was selected because a developmental endpoint was selected (30 mg/kg/day). A two hour duration on turfgrass will be used in this assessment representing the 95th percentile of time spent on lawns. This two hour value is based on human activity pattern data presented in the Agency's Exposure Factors Handbook.

For example:

- TTR = 0.02 $\mu\text{g}/\text{cm}^2$ (for Indiana)
- Trans. Co. = 70000 cm^2/hour
- Hours on turf = 2 hours/day
- Dermal absorption = 0.01
- Body weight = 60 kg

so that the calculation becomes:

$$\begin{aligned} \text{Dermal Exposure} &= \frac{0.02 \mu\text{g}/\text{cm}^2 * 70000 \text{ cm}^2/\text{hour} * 2 \text{ hours/day} * 0.01 * 1 \text{ mg}/1000 \text{ ug}}{60 \text{ kg}} \\ &\approx 0.0005 \text{ mg/kg/day} \end{aligned}$$

The MOE, then, is NOAEL (mg/kg/day) \div Dermal exposure (mg/kg/day). In the example:

$$\begin{aligned} \text{MOE} &= 30 \text{ mg/kg/day} \div 0.0005 \text{ mg/kg/day} \\ &= 60000 \end{aligned}$$

The time zero dermal exposure values for adult females reentering treated lawns based on the data in Table 4 and the rationale above are as follows:

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 18 of 44

Table 5. Adult Dermal Exposure and Risk Summary for Turf

Study Location	Time Zero Residue ($\mu\text{g}/\text{cm}^2$)	Adult Dermal Exposure (mg/kg/day)	Margin of Exposure ¹
Indiana	0.02	0.0005	60000
Pennsylvania	0.05	0.0012	25000
California	0.1	0.0023	13000
¹ MOE = NOAEL (30 mg/kg bw/day) / Estimated Dermal Exposure			

For children, the transfer coefficient is adjusted for a surface area of 6000 cm^2 /hour from an adult surface area of 1.8 m^2 . This transfer coefficient is 23,000 cm^2 . The body weight is 15 kg. The time zero exposure values for children reentering treated lawns based on the are as follows:

Table 6. Children's Dermal Exposure and Risk Summary for Turf

Study Location	Time Zero Residue ($\mu\text{g}/\text{cm}^2$)	Child Dermal Exposure (mg/kg/day)	Margin of Exposure ¹
Indiana	0.02	0.0006	150000
Pennsylvania	0.05	0.0015	60000
California	0.1	0.003	30000
¹ MOE = NOAEL (90 mg/kg bw/day) / Estimated Dermal Exposure			

Non-dietary Ingestion Exposure From Treated Turf

Non-dietary ingestion exposure levels from turf were calculated using the following equations. These values were then used to calculate MOEs as illustrated above. The following illustrates the approach used to calculate the non-dietary ingestion exposures that are attributable to hand-to-mouth behavior on treated turf (SOP 2.3.2):

$$D = (TTR * (SE/100) * SA * Freq * Hr * (1\text{mg}/1000\mu\text{g}))$$

where:

D = dose from hand-to-mouth activity (mg/day);

TTR = Turf Transferable Residue where dissipation is based on TTR

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 19 of 44

		study and the 0-day value is based on the 5% initial transferability factor ($\mu\text{g}/\text{cm}^2$);
SE	=	saliva extraction factor (50%);
SA	=	surface area of the hands (20 cm^2);
Freq	=	frequency of hand-to-mouth events (20 events/hour); and
Hr	=	exposure duration (2 hours).

Where, hand-to-mouth exposures are based on a frequency of 20 events/hour and a surface area per event of 20 cm^2 representing the palmar surfaces of three fingers; and

Saliva extraction efficiency is 50 percent meaning that every time the hand goes in the mouth approximately $\frac{1}{2}$ of the residues on the hand are removed.

The point of departure for comparing non-dietary ingestion exposure is 90 mg/kg/day and is based on a developmental study. The non-dietary estimate is 0.03 mg/kg/day and the MOE is 3000.

To evaluate potential to children who are exposed by both skin contact and incidental oral ingestion, the Agency calculated the MOE for combined exposure as:

$1 / (1/\text{MOE}_{\text{DERMAL}} + 1/\text{MOE}_{\text{ORAL}})$; note, the MOE for dermal exposure was derived from the California study.

$$\begin{aligned}\text{So, } \text{MOE}_{\text{COMBINED}} &= 1 / (1/30000 + 1/3000) \\ &= 2700\end{aligned}$$

Therefore, the Agency does not have any concerns for infant's combined dermal and incidental oral ingestion.

The dermal assessments are conservative because they assume reentry immediately after the application of propiconazole at the highest recommended rate of 1.79 pounds ai per acre. A conservative estimate of acres treated with propiconazole is 18,000 based on the assumption that all of the propiconazole available for the consumer market is applied to lawns. There are approximately 30 million acres of lawns in the United States according to Kline and Company. Therefore, less than 0.1 percent of the lawns are likely to be treated. That, coupled with the fact that the majority of use is likely to be in the midwest and northeastern United States, the exposure scenario represented by the California data is assumed to be worst case and assumed to be an unlikely event. Therefore, the Agency considers that exposures in excess of those calculated are unlikely.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 20 of 44

Occupational Exposure

It was necessary to conduct an assessment of worker exposure and risks to propiconazole. The toxicity information was taken from "Memo, J. Kidwell, TXR NO 0052277, PROPICONAZOLE - 3rd Report of the Hazard Identification Assessment Review Committee, 17 DEC 2003." A short-term (1 - 30 days) dermal point of departure (NOAEL 30 mg a.i./kg bw/day) was identified from a rat developmental toxicity study. The effects seen were increased incidence of rudimentary ribs, cleft palate malformations, unossified sternbrae, as well as increased incidence of shortened and absent renal papillae. A dermal absorption factor of 1% was identified (J. Evans email previously cited). A short-term inhalation NOAEL (30 mg a.i./kg bw/day) was identified from the same study as the dermal NOAELs and the same effects listed.

ADD for propiconazole =

Unit Exposure * Application Rate * Units Treated * 1 % dermal absorption ÷ 60 kg bw
(Inhalation = 100 % absorption)

Since the dermal and inhalation toxicological effects are the same and identified from the same study, the exposures are summed then divided into the NOAEL. The occupational risk assessment is summarized in Table 7.

Table 7. Summary of Exposures and Risks to Occupational Pesticide Handlers to Propiconazole Used to Control Soybean Rust					
Unit Exposure¹ mg/lb ai handled	Application Rate² lb ai/Acre	Units Treated³ Acres/Day	Average Daily Dose⁴ mg a.i./kg bw/day	NOAEL⁵ mg a.i./kg bw/day	MOE⁶
Mixer/Loader - Liquid - Open Loading					
Dermal: SLNG 2.9 HC SLWG 0.023 HC Inhal 0.0012HC	3.6 oz ai/A 0.225 lb ai/A	1200 A	Dermal: SLNG 0.13 SLWG 0.001 Inhalation 0.0054	Dermal (1 % D.A.) 30 Inhalation 30.0	SLNG 220 SLWG 4700
Applicator - Ground-boom - Open Cab					
Dermal: SLNG 0.014 HC SLWG 0.014 MC Inhal 0.00074HC	3.6 oz ai/A 0.225 lb ai/A	200 A	Dermal SLNG 0.0001 SLWG 0.0001 Inhalation 0.00056	Dermal 30 (1 % D.A.) Inhalation 30.0	SLNG 45000 SLWG 45000
Applicator - Aerial - Fixed Wing					

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 21 of 44

Table 7. Summary of Exposures and Risks to Occupational Pesticide Handlers to Propiconazole Used to Control Soybean Rust

Dermal: SLNG 0.0050 MC	3.6 oz ai/A 0.225 lb ai/A	1200 A	Dermal SLNG 0.00023	Dermal (1 % D.A.) F 13-50 30 Gen Pop 90	F 13-50 56000 Gen Pop 170000
Inhal 0.000068 MC			Inhalation 0.00031	Inhalation 30.0	

1. Unit Exposure = mg a.i./lb a.i. handled from PHED SURROGATE EXPOSURE GUIDE - Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1, August 1998. Dermal: SLNG = a Single Layer of work clothing (i.e., long pants, long-sleeved shirt, shoes plus socks) and No protective gloves. SLWG = a single layer of work clothing and the use of protective gloves (i.e., with gloves). Inhal = Inhalation exposure. HC and MC are data quality descriptors: High Confidence and Medium Confidence, respectively.

2. Application Rate taken from Section 18 Request, Corresp. J. Sierk Minnesota Dept. Agricult. to D. Rosenblatt, 30 January 2004.

3. Units Treated taken from Science Advisory Council for Exposure, Standard Operating Procedure 9.1, Standard Values for Daily Acres Treated in Agriculture, Rev. 25 SEP 2001.

4. Average Daily Dose (ADD) is derived by: (See "Discussion" listed by compound).
Unit Exposure * Application Rate * Units Treated * Absorption Factor (when applicable) ÷ Body Weight.

NOTE a) Dermal absorption is not corrected if the toxicological endpoints were identified from a dermal toxicity study. Otherwise, the dermal absorption factor is utilized as identified by the HED HIARC. Inhalation absorption is assumed to be 100 %.

NOTE b) Body weight is assumed to be 70 kg unless the toxicological endpoints (NOAEL) are identified from a developmental study which showed fetal effects. Then, 60 kg bw is used.

5. No Observed Adverse Effect Level (NOAEL) (mg a.i./kg bw/day) are taken from the HED Hazard Identification Assessment Review Committee (HIARC) for each compound discussed herein.

6. Margin Of Exposure (MOE) = NOAEL (mg a.i./kg bw/day) ÷ ADD (mg a.i./kg bw/day).

There is a potential for agricultural workers to have post-application exposure to pesticides during the course of typical agricultural activities. HED in conjunction with the Agricultural Re-entry Task Force (ARTF) has identified a number of post-application agricultural activities that may occur. HED has also identified Transfer Coefficients (TC) (expressed as cm²/hr) relative to the various activities.

The transfer coefficients used in this assessment are from an interim transfer coefficient SOP developed by HED's Science Advisory Council for Exposure using proprietary data from the Agricultural Re-Entry Task Force (ARTF) database (SOP # 3.1). It is the intention of HED's

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 22 of 44

Science Advisory Council for Exposure that this SOP will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from further analysis of studies already submitted to the Agency, and from studies in the published scientific literature.

For the proposed use, the activity with the highest TC is scouting the crop in full foliage stages of crop development with a TC of 1,500 cm²/hr.

Lacking compound specific data, the Agency assumes 20 % of the application rate is available as foliar dislodgeable residue on day zero after application. This is adapted from the Science Advisory Council For Exposure SOP No. 003 (7 May 1998 - Revised 7 August 2000). The following convention may be used to estimate post-application exposure.

Surrogate Dislodgeable Foliar Residue

DFR =

$$\text{application rate} * 20\% \text{ available as dislodgeable residue} * (1-D)^t * 4.54 \times 10^8 \mu\text{g/lb} * 2.47 \times 10^{-8} \text{ A/cm}^2$$

Note: the term $(1-D)^t$ describes the fraction of the residue remaining after “t” days.

and the Average Daily Dose (ADD) =

$$\text{DFR } \mu\text{g/cm}^2 * \text{TC cm}^2/\text{hr} * \text{hr/day} * 0.001 \text{ mg}/\mu\text{g} * 1/70 \text{ kg bw}$$

For propiconazole, the calculations are:

$$\begin{aligned} \text{DFR} &= 0.225 \text{ lb a.i./A} * .20 * (1-0)^0 * 4.54 \times 10^8 \mu\text{g/lb} * 2.47 \times 10^{-8} \text{ A/cm}^2 \\ &= 0.5 \mu\text{g/cm}^2 \end{aligned}$$

$$\begin{aligned} \text{ADD} &= 0.5 \mu\text{g/cm}^2 * 1,500 \text{ cm}^2/\text{hr} * 8 \text{ hr/day} * 0.001 \text{ mg}/\mu\text{g} * \\ &\quad 1 \% \text{ dermal absorption} * 1/60 \text{ kg bw} \\ &= 0.001 \text{ mg/kg bw/day} \end{aligned}$$

$$\begin{aligned} \text{Since MOE} &= \text{NOAEL} \div \text{ADD then } 30 \text{ mg/kg bw/day} \div 0.001 \text{ mg/kg bw/day} \\ &= 30000 \text{ for females } 13 - 50 \end{aligned}$$

$$\begin{aligned} \text{For the general population } &90 \text{ mg a.i./kg bw/day} \div 0.001 \text{ mg a.i./kg bw/day} \\ &= 90000 \end{aligned}$$

Aggregate Exposure and Risk

Aggregate exposure risk assessments were performed for acute (food + drinking water), chronic (food + drinking water) and short-term (food + drinking water + residential) aggregate exposure. In the absence of ground and surface water monitoring data to calculate a quantitative aggregate

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 23 of 44

exposure, drinking water levels of comparison (DWLOCs) were calculated. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. HED uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water.

DWLOCs were calculated for acute and chronic exposure to propiconazole in surface and ground water. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from DEEM™) was subtracted from the aPAD to obtain the acceptable acute exposure to propiconazole in drinking water. To calculate the DWLOC for chronic exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM™) was subtracted from the cPAD to obtain the acceptable chronic exposure to propiconazole in drinking water. DWLOCs were calculated using the standard body weights and drinking water consumption figures: 70 kg/2L (adult male and US Population), 60 kg/2L (adult female), and 10 kg/1L (infant and children).

To calculate short-term DWLOCs average dietary exposure from food and residential exposure are both subtracted from the target maximum exposure (NOAEL/Target MOE) to obtain the allowable average exposure of propiconazole in drinking water.

The aggregate exposure risk assessments (acute, short-term, and chronic) are considered conservative estimates that are unlikely to underestimate risks, because of the following inputs: 1) dietary inputs used conservative Tier I DEEM analyses; 2) maximum application rates and minimum application intervals were used; and 3) conservative SOPs and upper level estimates of exposure were employed.

Aggregate Acute Risk

The aggregate acute dietary risk estimates include exposure to residues of propiconazole in food and water, and does not include dermal, inhalation or incidental oral exposure. As shown in Table 8, the estimated peak concentration of propiconazole in surface water and the estimated acute concentrations in shallow ground water are considerably lower than the DWLOCs for all population subgroups. Therefore, the acute aggregate risk estimates for adults and children do not exceed HED's level of concern.

Table 8. Acute Aggregate Exposure and Risk Summary							
Acute Exposure	aPAD	Food Exposure	BW (kg)	Water (L)	DWLOC ¹ in ppb	EEC in ppb	
						GW ²	SW ³

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 24 of 44

General U.S. Population	0.3	0.005540	70	2	10000	264	1.5
All Infants (< 1 year old)	0.3	0.013057	10	1	2900		
Children 1-2 years old	0.3	0.012848	10	1	2900		
Children 3-5 years old	0.3	0.010216	10	1	2900		
Children 6-12 years old	0.3	0.006745	10	1	2900		
Youth 13-19 years old	0.3	0.003983	60	2	8900		
Adults 20-49 years old	0.3	0.003809	70	2	10000		
Adults 50+	0.3	0.004062	70	2	10000		
Females 13-49 years old	0.1	0.003854	60	2	2900		
DWLOC(µg/L) = $\frac{[\text{maximum water exposure (mg/kg/day)} \times \text{body weight (kg)}]}{[\text{water consumption (L)} \times 10^{-3} \text{ mg/}\mu\text{g}]}$							
Where Maximum Water Exposure (mg/kg/day) = PAD (mg/kg/day) - Food Exposure from DEEM (mg/kg/day).							
† Based upon SCI-GROW modeling results.							
‡ Based upon PRZM/EXAMS modeling results.							

Aggregate Short-Term Risk

The short-term aggregate risk assessment takes into account average exposures estimates from dietary consumption of propiconazole (food and drinking water) and non-occupational uses (turf). Postapplication exposures from the use on turf is considered *short-term*. Therefore, a short-term aggregate risk assessment was conducted, using children with combined dermal and oral exposures from the turf use as a worst case. Table 9 summarizes the results. The MOE from food and non-occupational uses is 2400, and the calculated short-term DWLOC is 2600 ppb. Compared to EFED's surface and ground water EECs, the DWLOC is greater, and therefore, short-term aggregate risk does not exceed HED's level of concern.

Table 9. Short-Term Aggregate Risk and DWLOC Calculations

Population	Short-Term Scenario								
	NOAEL mg/kg/day	Max Exposure ¹ mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure ² mg/kg/day	Aggregate MOE ³	Max Water Exposure ⁴ mg/kg/day	Surface Water EEC ⁵ (ppb)	Ground Water EEC ⁶ (ppb)	Short- Term DWLOC ^{7,8} (µg/L)
All Infants ⁸	90	0.3	0.003736	0.033	2400	0.263	264	1.50	2600

¹ Maximum Exposure (mg/kg/day) = NOAEL/Target MOE of 300
² Residential Exposure = Combined dermal and incidental oral ingestion for infants. Only infants were assessed since they represent a worst case with their higher food exposure plus incidental oral exposure to treated turf.
³ Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]
⁴ Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
⁵ Using maximum application parameters, calculated using FIRST
⁶ Using maximum application parameters, calculated using SCI-GROW
⁷ DWLOC(µg/L) = $\frac{\text{maximum water exposure (mg/kg/day)} \times \text{body weight (10 kg)}}{\text{water consumption (1 L)} \times 10^{-3} \text{ mg/}\mu\text{g}}$
⁸ Assuming body weight of 10 kg and water consumption of 1L

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 26 of 44

Aggregate Chronic Risk

The aggregate chronic risk assessment takes into account average exposure estimates from dietary consumption of propiconazole (food and drinking water) and residential uses. Since the exposure from turf is considered short-term, the aggregate chronic assessment included food and drinking water only. The calculated chronic DWLOCs for chronic exposure to propiconazole in drinking water range from 940 to 3400 µg/L (ppb). EECs generated by FIRST and SCI-GROW are less than calculated chronic DWLOCs (Table 10). Therefore, the aggregate chronic risk associated with the proposed use of propiconazole does not exceed the Agency's level of concern for the general U.S. population or any population subgroup.

Table 10. Chronic Aggregate Exposure and Risk Summary							
Chronic Exposure	PAD	Exposure	BW (kg)	Water (L)	DWLOC ¹ in ppb	EEC in ppb	
						GW ²	SW ³
General U.S. Population	0.1	0.001984	70	2	3400	80	1.5
All Infants (< 1 year old)	0.1	0.003736	10	1	960		
Children 1-2 years old	0.1	0.005877	10	1	940		
Children 3-5 years old	0.1	0.004615	10	1	950		
Children 6-12 years old	0.1	0.003007	10	1	970		
Youth 13-19 years old	0.1	0.001728	60	2	2900		
Adults 20-49 years old	0.1	0.001478	70	2	3400		
Adults 50+ years old	0.1	0.001494	70	2	3400		
Females 13-49 years old	0.1	0.000859	60	2	3000		
DWLOC(µg/L) = $\frac{[\text{maximum water exposure (mg/kg/day)} \times \text{body weight (kg)}]}{[\text{water consumption (L)} \times 10^{-3} \text{ mg/}\mu\text{g}]}$							
¹ Based upon FIRST modeling results.							
² Based upon SCI-GROW modeling results.							

VI. Characterization of Inputs/Outputs

All residue values used for estimating dietary exposure and risk (both acute and chronic) were tolerances from 40 CFR § 180.434, with the exception of soybean, the subject of the Section 18 request. Since the available residue data for soybeans do not exceed the existing tolerance for dry beans tolerance from 40 CFR § 180.434, a temporary tolerance of 0.5 ppm is recommended

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 27 of 44

for soybeans. This value is consistent with a previous review of soybean residue data (DP Barcodes D210266 and D210295; previously cited).

Both the acute and chronic dietary risk assessments should be considered unrefined because 1) tolerance level residues were assumed, 2) 100% of all crops were assumed to be treated and 3) DEEM™ default concentration factors were assumed for processed commodities.

Residential and occupational risk assessments used default assumptions and are also conservative risk estimates. Finally, aggregate risk was estimated using published procedures and were not refined.

VII. Endocrine Disrupter Effects

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disrupter Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disrupter Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, propiconazole may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

VIII. Cumulative Exposure to Substance with a Common Mechanism of Toxicity

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 28 of 44

substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

HED did not perform a cumulative risk assessment as part of this risk assessment for propiconazole because data to determine the extent to which other chemical substances have a mechanism of toxicity common with that of propiconazole are not yet available. For purposes of this Section 18 petition, only parent propiconazole is being considered. The Agency does have concern about potential toxicity to 1,2,4-triazole and two conjugates, triazolylalanine and triazolyl acetic acid, metabolites common to most of the triazole fungicides. When suitable information about the toxicity of these compounds is available, the Agency may revisit the risk issues.

On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether propiconazole shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for propiconazole need to be modified or revoked. If HED identifies other substances that share a common mechanism of toxicity with propiconazole, HED will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment.

HED has recently finalized its guidance for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance will be available from the OPP Website (<http://www.epa.gov/pesticides>). In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the *Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity* (64 FR 5795-5796, February 5, 1999).

IX. Conclusions

Both the acute and chronic risk assessments used worst-case assumptions to provide a highly protective estimate of exposure and risk. Regarding acute dietary risk, the most highly exposed population group at the 95th exposure percentile (All infants) had estimated exposure of 0.013057 mg/kg bw/day, equivalent to 4% of the aPAD. All other groups, including females 13-49 had exposures less than this value. The most highly exposed group relative to chronic dietary exposure was Children 1-2, with an estimated exposure of 0.005877 mg/kg bw/day, or approximately 6% of the cPAD. All other population groups had estimated exposures less than this value. Given the protective assumptions used in the risk assessment, both acute and chronic dietary exposures from the use of propiconazole to control soybean rust as specified in the

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 29 of 44

Section 18 request result in acceptable levels of safety for all population sub-groups.

DWLOC methodology was used to assess acute and chronic risks from residues in water via comparison with EECs provided by EFED. This comparison demonstrated that such risks are below the Agency's level of concern. Residential and occupational exposures and risks were lower than the threshold for the Agency to be concerned. An assessment of short-term aggregate risk demonstrates MOEs below the Agency's level of concern.

Given the protective assumptions used in the risk assessment, risks associated with the Section 18 request result in acceptable levels of safety for all population sub-groups.

Based upon these risk assessments, the Section 18 request for the use of propiconazole on soybean is not expected to adversely affect human health. The available data support time-limited tolerances of 0.5 ppm in soybeans, 8 ppm in soybean forage and 25 ppm in soybean hay.

X. List of Attachments

Attachment 1 - Acute and Chronic Residue Input file.

- Attachment 2 - Results of the Acute Dietary Risk Assessment.
- Attachment 3 - Results of the Chronic Dietary Risk Assessment

cc: M Waller, Fungicides Branch, Registration Division (7505C)
M. Doherty, Registration Action Branch 2, Health Effects Division (7509C)
J. R. Tomerlin, Fungicides Branch, Registration Division (7505C)

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 30 of 44

ATTACHMENT 1 - Residue File Listing for Acute and Chronic Dietary Assessments

U.S. Environmental Protection Agency
DEEM-FCID Chronic analysis for PROPICONAZOLE
Residue file: C:\Documents and Settings\btomerli\My
Documents\tzoles\risk\dietary\prop\prop-tol.R98

Ver. 1.30
1994-98 data

Adjust. #2 NOT used

Analysis Date 02-02-2004 Residue file dated: 02-02-2004/13:18:51/8
Reference dose (RfD) = 0.1 mg/kg bw/day
Comment:Acute for general popn - 0.3 (0.1 is for females)

Food Crop			Residue (ppm)	Adj.Factors		Comment
EPA Code	Grp	Food Name		#1	#2	
12000120	12	Apricot	1.000000	1.000	1.000	
12000121	12	Apricot-babyfood	1.000000	1.000	1.000	
12000130	12	Apricot, dried	1.000000	6.000	1.000	
12000140	12	Apricot, juice	1.000000	1.000	1.000	
12000141	12	Apricot, juice-babyfood	1.000000	1.000	1.000	
95000230	0	Banana	0.200000	1.000	1.000	
95000231	0	Banana-babyfood	0.200000	1.000	1.000	
95000240	0	Banana, dried	0.200000	3.900	1.000	
95000241	0	Banana, dried-babyfood	0.200000	3.900	1.000	
15000250	15	Barley, pearled barley	0.100000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000	
15000260	15	Barley, flour	0.100000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000	
15000270	15	Barley, bran	0.100000	1.000	1.000	
06030300	6C	Bean, black, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030320	6C	Bean, broad, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030340	6C	Bean, cowpea, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030350	6C	Bean, great northern, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030360	6C	Bean, kidney, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030380	6C	Bean, lima, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030390	6C	Bean, mung, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030400	6C	Bean, navy, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030410	6C	Bean, pink, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030420	6C	Bean, pinto, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
21000440	M	Beef, meat	0.100000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.100000	1.000	1.000	
21000450	M	Beef, meat, dried	0.100000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.100000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.100000	1.000	1.000	
21000470	M	Beef, fat	0.100000	1.000	1.000	
21000471	M	Beef, fat-babyfood	0.100000	1.000	1.000	
21000480	M	Beef, kidney	2.000000	1.000	1.000	
21000490	M	Beef, liver	2.000000	1.000	1.000	
21000491	M	Beef, liver-babyfood	2.000000	1.000	1.000	
04020850	4B	Celery	5.000000	1.000	1.000	
04020851	4B	Celery-babyfood	5.000000	1.000	1.000	
04020860	4B	Celery, juice	5.000000	1.000	1.000	

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 31 of 44

12000900	12	Cherry	1.000000	1.000	1.000	
12000901	12	Cherry-babyfood	1.000000	1.000	1.000	
12000910	12	Cherry, juice	1.000000	1.500	1.000	
12000911	12	Cherry, juice-babyfood	1.000000	1.500	1.000	
40000930	P	Chicken, meat	0.100000	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.100000	1.000	1.000	
40000940	P	Chicken, liver	0.200000	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.100000	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.100000	1.000	1.000	
40000960	P	Chicken, fat	0.100000	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.100000	1.000	1.000	
40000970	P	Chicken, skin	0.100000	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.100000	1.000	1.000	
06030980	6C	Chickpea, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030981	6C	Chickpea, seed-babyfood	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06030990	6C	Chickpea, flour	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
15001200	15	Corn, field, flour	0.100000	1.000	1.000	
15001201	15	Corn, field, flour-babyfood	0.100000	1.000	1.000	
15001210	15	Corn, field, meal	0.100000	1.000	1.000	
15001211	15	Corn, field, meal-babyfood	0.100000	1.000	1.000	
15001220	15	Corn, field, bran	0.100000	1.000	1.000	
15001230	15	Corn, field, starch	0.100000	1.000	1.000	
15001231	15	Corn, field, starch-babyfood	0.100000	1.000	1.000	
15001240	15	Corn, field, syrup	0.100000	1.500	1.000	
15001241	15	Corn, field, syrup-babyfood	0.100000	1.500	1.000	
15001250	15	Corn, field, oil	0.100000	1.000	1.000	
15001251	15	Corn, field, oil-babyfood	0.100000	1.000	1.000	
15001270	15	Corn, sweet	0.100000	1.000	1.000	
15001271	15	Corn, sweet-babyfood	0.100000	1.000	1.000	
95001300	O	Cranberry	1.000000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
95001301	O	Cranberry-babyfood	1.000000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
95001310	O	Cranberry, dried	1.000000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
95001320	O	Cranberry, juice	1.000000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
95001321	O	Cranberry, juice-babyfood	1.000000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
70001450	P	Egg, whole	0.100000	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.100000	1.000	1.000	
70001460	P	Egg, white	0.100000	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.100000	1.000	1.000	
70001470	P	Egg, yolk	0.100000	1.000	1.000	
70001471	P	Egg, yolk-babyfood	0.100000	1.000	1.000	
23001690	M	Goat, meat	0.100000	1.000	1.000	
23001700	M	Goat, meat byproducts	0.100000	1.000	1.000	
23001710	M	Goat, fat	0.100000	1.000	1.000	
23001720	M	Goat, kidney	2.000000	1.000	1.000	
23001730	M	Goat, liver	2.000000	1.000	1.000	
06031820	6C	Guar, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
06031821	6C	Guar, seed-babyfood	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
24001890	M	Horse, meat	0.100000	1.000	1.000	
06032030	6C	Lentil, seed	0.500000	1.000	1.000	Exp 12
Full comment: Exp 12/31/05						
27002220	D	Milk, fat	0.050000	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.050000	1.000	1.000	

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299

Page: 32 of 44

27012230	D	Milk, nonfat solids	0.050000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.050000	1.000	1.000
27022240	D	Milk, water	0.050000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.050000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.050000	1.000	1.000
95002280	O	Mushroom	0.100000	1.000	1.000
12002300	12	Nectarine	1.000000	1.000	1.000
15002310	15	Oat, bran	0.100000	1.000	1.000
15002320	15	Oat, flour	0.100000	1.000	1.000
15002321	15	Oat, flour-babyfood	0.100000	1.000	1.000
15002330	15	Oat, groats/rolled oats	0.100000	1.000	1.000
15002331	15	Oat, groats/rolled oats-babyfood	0.100000	1.000	1.000
12002600	12	Peach	1.000000	1.000	1.000
12002601	12	Peach-babyfood	1.000000	1.000	1.000
12002610	12	Peach, dried	1.000000	7.000	1.000
12002611	12	Peach, dried-babyfood	1.000000	7.000	1.000
12002620	12	Peach, juice	1.000000	1.000	1.000
12002621	12	Peach, juice-babyfood	1.000000	1.000	1.000
95002630	O	Peanut	0.200000	1.000	1.000
95002640	O	Peanut, butter	0.200000	1.890	1.000
95002650	O	Peanut, oil	0.200000	1.000	1.000
14002690	14	Pecan	0.100000	1.000	1.000
95002750	O	Peppermint	0.300000	1.000	1.000
95002790	O	Pineapple	0.100000	1.000	1.000
95002791	O	Pineapple-babyfood	0.100000	1.000	1.000
95002800	O	Pineapple, dried	0.100000	5.000	1.000
95002810	O	Pineapple, juice	0.100000	1.700	1.000
95002811	O	Pineapple, juice-babyfood	0.100000	1.700	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
12002850	12	Plum	1.000000	1.000	1.000
12002851	12	Plum-babyfood	1.000000	1.000	1.000
12002860	12	Plum, prune, fresh	1.000000	1.000	1.000
12002861	12	Plum, prune, fresh-babyfood	1.000000	1.000	1.000
12002870	12	Plum, prune, dried	1.000000	5.000	1.000
12002871	12	Plum, prune, dried-babyfood	1.000000	5.000	1.000
12002880	12	Plum, prune, juice	1.000000	1.400	1.000
12002881	12	Plum, prune, juice-babyfood	1.000000	1.400	1.000
25002900	M	Pork, meat	0.100000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.100000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.100000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.100000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	2.000000	1.000	1.000
25002950	M	Pork, liver	2.000000	1.000	1.000
60003010	P	Poultry, other, meat	0.100000	1.000	1.000
60003020	P	Poultry, other, liver	0.200000	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.100000	1.000	1.000
60003040	P	Poultry, other, fat	0.100000	1.000	1.000
60003050	P	Poultry, other, skin	0.100000	1.000	1.000
15003230	15	Rice, white	0.100000	1.000	1.000
15003231	15	Rice, white-babyfood	0.100000	1.000	1.000
15003240	15	Rice, brown	0.100000	1.000	1.000
15003241	15	Rice, brown-babyfood	0.100000	1.000	1.000
15003250	15	Rice, flour	0.100000	1.000	1.000
15003251	15	Rice, flour-babyfood	0.100000	1.000	1.000
15003260	15	Rice, bran	0.100000	1.000	1.000
15003261	15	Rice, bran-babyfood	0.100000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 33 of 44

26003390 M	Sheep, meat	0.100000	1.000	1.000	
26003391 M	Sheep, meat-babyfood	0.100000	1.000	1.000	
26003400 M	Sheep, meat byproducts	0.100000	1.000	1.000	
26003410 M	Sheep, fat	0.100000	1.000	1.000	
26003411 M	Sheep, fat-babyfood	0.100000	1.000	1.000	
26003420 M	Sheep, kidney	2.000000	1.000	1.000	
26003430 M	Sheep, liver	2.000000	1.000	1.000	
15003440 15	Sorghum, grain	0.200000	1.000	1.000	Exp 6/
Full comment: Exp 6/30/05					
15003450 15	Sorghum, syrup	0.200000	1.000	1.000	Exp 6/
Full comment: Exp 6/30/05					
06003470 6	Soybean, seed	0.500000	1.000	1.000	
06003480 6	Soybean, flour	0.500000	1.000	1.000	
06003481 6	Soybean, flour-babyfood	0.500000	1.000	1.000	
06003490 6	Soybean, soy milk	0.500000	1.000	1.000	
06003491 6	Soybean, soy milk-babyfood or in	0.500000	1.000	1.000	
06003500 6	Soybean, oil	0.500000	1.000	1.000	
06003501 6	Soybean, oil-babyfood	0.500000	1.000	1.000	
50003820 P	Turkey, meat	0.100000	1.000	1.000	
50003821 P	Turkey, meat-babyfood	0.100000	1.000	1.000	
50003830 P	Turkey, liver	0.200000	1.000	1.000	
50003831 P	Turkey, liver-babyfood	0.200000	1.000	1.000	
50003840 P	Turkey, meat byproducts	0.100000	1.000	1.000	
50003841 P	Turkey, meat byproducts-babyfood	0.100000	1.000	1.000	
50003850 P	Turkey, fat	0.100000	1.000	1.000	
50003851 P	Turkey, fat-babyfood	0.100000	1.000	1.000	
50003860 P	Turkey, skin	0.100000	1.000	1.000	
50003861 P	Turkey, skin-babyfood	0.100000	1.000	1.000	
15004010 15	Wheat, grain	0.100000	1.000	1.000	
15004011 15	Wheat, grain-babyfood	0.100000	1.000	1.000	
15004020 15	Wheat, flour	0.100000	1.000	1.000	
15004021 15	Wheat, flour-babyfood	0.100000	1.000	1.000	
15004030 15	Wheat, germ	0.100000	1.000	1.000	
15004040 15	Wheat, bran	0.100000	1.000	1.000	
15004050 15	Wild rice	0.500000	1.000	1.000	

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 34 of 44

ATTACHMENT 2 - Acute Dietary Risk Assessment

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
U.S. Population:	0.005540	1.85	0.010327	3.44	0.021349	7.12
All infants (<1 yr old):	0.013057	4.35	0.019229	6.41	0.030359	10.128
Children 1-2 yrs:	0.012848	4.28	0.023539	7.85	0.053830	17.94
Children 3-5 yrs:	0.010216	3.41	0.017398	5.80	0.030156	10.05
Children 6-12 yrs:	0.006745	2.25	0.011618	3.87	0.027832	9.28
Youth 13-19 yrs:	0.003983	1.33	0.007363	2.45	0.013799	4.60
Adults 20-49 yrs:	0.003809	1.27	0.006201	2.07	0.011602	3.87
Adults 50+ yrs:	0.004062	1.35	0.007085	2.36	0.013518	4.51
Females 13-49 yrs:	0.003854	3.85	0.006261	6.26	0.010792	10.79

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299

Page: 35 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

U.S. Population

Daily Exposure Analysis /a
(mg/kg body-weight/day)
per Capita per User

Mean	0.001984	0.001989
Standard Deviation	0.002142	0.002142
Standard Error of mean	0.000011	0.000011
Percent of aRfD	0.66	0.66

Percent of Person-Days that are User-Days = 99.74%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000531	0.18	90.00	0.004073	1.36
20.00	0.000730	0.24	95.00	0.005546	1.85
30.00	0.000917	0.31	97.50	0.007281	2.43
40.00	0.001117	0.37	99.00	0.010339	3.45
50.00	0.001349	0.45	99.50	0.013130	4.38
60.00	0.001648	0.55	99.75	0.016571	5.52
70.00	0.002098	0.70	99.90	0.021361	7.12
80.00	0.002791	0.93			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000526	0.18	90.00	0.004068	1.36
20.00	0.000726	0.24	95.00	0.005540	1.85
30.00	0.000913	0.30	97.50	0.007273	2.42
40.00	0.001114	0.37	99.00	0.010327	3.44
50.00	0.001346	0.45	99.50	0.013117	4.37
60.00	0.001645	0.55	99.75	0.016566	5.52
70.00	0.002094	0.70	99.90	0.021349	7.12
80.00	0.002787	0.93			

a/ Analysis based on all two-day participant records in CSFII 1994-98 survey.

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 36 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Nursing infants (<1 yr old)	Daily Exposure Analysis	
	(mg/kg body-weight/day)	
-----	per Capita	per User
Mean	0.001779	0.002885
Standard Deviation	0.003306	0.003812
Standard Error of mean	0.000114	0.000163
Percent of aRfD	0.59	0.96

Percent of Person-Days that are User-Days = 61.64%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000202	0.07	90.00	0.007657	2.55
20.00	0.000406	0.14	95.00	0.012229	4.08
30.00	0.000642	0.21	97.50	0.015080	5.03
40.00	0.000960	0.32	99.00	0.017405	5.80
50.00	0.001265	0.42	99.50	0.018484	6.16
60.00	0.001963	0.65	99.75	0.019293	6.43
70.00	0.002980	0.99	99.90	0.023100	7.70
80.00	0.004437	1.48			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.00	90.00	0.005461	1.82
20.00	0.000000	0.00	95.00	0.008952	2.98
30.00	0.000000	0.00	97.50	0.013081	4.36
40.00	0.000052	0.02	99.00	0.016824	5.61
50.00	0.000373	0.12	99.50	0.017462	5.82
60.00	0.000799	0.27	99.75	0.018549	6.18
70.00	0.001348	0.45	99.90	0.020034	6.68
80.00	0.002758	0.92			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 37 of 44

U.S. Environmental Protection Agency
DEEM-FCID ACUTE Analysis for PROPICONAZOLE
Residue file: prop-tol.R98
Analysis Date: 02-02-2004/13:33:01
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Ver. 1.33

(1994-98 data)

Adjustment factor #2 NOT used.

Residue file dated: 02-02-2004/13:18:51/8

Children 1-2 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean	0.005877	0.005878
Standard Deviation	0.004734	0.004733
Standard Error of mean	0.000073	0.000073
Percent of aRfD	1.96	1.96

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.002368	0.79	90.00	0.010138	3.38
20.00	0.003075	1.02	95.00	0.012849	4.28
30.00	0.003673	1.22	97.50	0.016852	5.62
40.00	0.004231	1.41	99.00	0.023540	7.85
50.00	0.004796	1.60	99.50	0.031957	10.65
60.00	0.005450	1.82	99.75	0.047534	15.84
70.00	0.006378	2.13	99.90	0.053830	17.94
80.00	0.007636	2.55			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.002366	0.79	90.00	0.010138	3.38
20.00	0.003073	1.02	95.00	0.012848	4.28
30.00	0.003673	1.22	97.50	0.016840	5.61
40.00	0.004231	1.41	99.00	0.023539	7.85
50.00	0.004796	1.60	99.50	0.031956	10.65
60.00	0.005450	1.82	99.75	0.047533	15.84
70.00	0.006377	2.13	99.90	0.053830	17.94
80.00	0.007635	2.55			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 38 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Children 3-5 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean	0.004615	0.004616
Standard Deviation	0.003169	0.003169
Standard Error of mean	0.000034	0.000034
Percent of aRfD	1.54	1.54

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.002091	0.70	90.00	0.007747	2.58
20.00	0.002587	0.86	95.00	0.010217	3.41
30.00	0.002967	0.99	97.50	0.013260	4.42
40.00	0.003412	1.14	99.00	0.017400	5.80
50.00	0.003826	1.28	99.50	0.021383	7.13
60.00	0.004310	1.44	99.75	0.027171	9.06
70.00	0.004999	1.67	99.90	0.030156	10.05
80.00	0.005887	1.96			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.002090	0.70	90.00	0.007746	2.58
20.00	0.002586	0.86	95.00	0.010216	3.41
30.00	0.002966	0.99	97.50	0.013258	4.42
40.00	0.003411	1.14	99.00	0.017398	5.80
50.00	0.003826	1.28	99.50	0.021383	7.13
60.00	0.004310	1.44	99.75	0.027171	9.06
70.00	0.004998	1.67	99.90	0.030156	10.05
80.00	0.005887	1.96			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 39 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Children 6-12 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean	0.003007	0.003007
Standard Deviation	0.002319	0.002319
Standard Error of mean	0.000036	0.000036
Percent of aRfD	1.00	1.00

Percent of Person-Days that are User-Days = 100.00%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.001181	0.39	90.00	0.005171	1.72
20.00	0.001550	0.52	95.00	0.006745	2.25
30.00	0.001850	0.62	97.50	0.008937	2.98
40.00	0.002148	0.72	99.00	0.011618	3.87
50.00	0.002481	0.83	99.50	0.015866	5.29
60.00	0.002814	0.94	99.75	0.017474	5.82
70.00	0.003270	1.09	99.90	0.027832	9.28
80.00	0.003942	1.31			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.001181	0.39	90.00	0.005171	1.72
20.00	0.001550	0.52	95.00	0.006745	2.25
30.00	0.001850	0.62	97.50	0.008937	2.98
40.00	0.002148	0.72	99.00	0.011618	3.87
50.00	0.002481	0.83	99.50	0.015866	5.29
60.00	0.002814	0.94	99.75	0.017474	5.82
70.00	0.003270	1.09	99.90	0.027832	9.28
80.00	0.003942	1.31			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299

Page: 40 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

-----	Daily Exposure Analysis (mg/kg body-weight/day)	
	per Capita	per User
-----	-----	-----
Mean	0.001728	0.001730
Standard Deviation	0.001351	0.001350
Standard Error of mean	0.000027	0.000027
Percent of aRfD	0.58	0.58

Percent of Person-Days that are User-Days = 99.90%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000621	0.21	90.00	0.003175	1.06
20.00	0.000833	0.28	95.00	0.003984	1.33
30.00	0.001021	0.34	97.50	0.005089	1.70
40.00	0.001201	0.40	99.00	0.007365	2.45
50.00	0.001397	0.47	99.50	0.008583	2.86
60.00	0.001617	0.54	99.75	0.010921	3.64
70.00	0.001924	0.64	99.90	0.013799	4.60
80.00	0.002306	0.77			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000619	0.21	90.00	0.003175	1.06
20.00	0.000831	0.28	95.00	0.003983	1.33
30.00	0.001020	0.34	97.50	0.005088	1.70
40.00	0.001200	0.40	99.00	0.007363	2.45
50.00	0.001396	0.47	99.50	0.008582	2.86
60.00	0.001616	0.54	99.75	0.010921	3.64
70.00	0.001923	0.64	99.90	0.013799	4.60
80.00	0.002305	0.77			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 41 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Adults 20-49 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean	0.001478	0.001481
Standard Deviation	0.001296	0.001296
Standard Error of mean	0.000013	0.000013
Percent of aRfD	0.49	0.49

Percent of Person-Days that are User-Days = 99.82%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000494	0.16	90.00	0.002877	0.96
20.00	0.000663	0.22	95.00	0.003811	1.27
30.00	0.000810	0.27	97.50	0.004768	1.59
40.00	0.000962	0.32	99.00	0.006203	2.07
50.00	0.001135	0.38	99.50	0.007607	2.54
60.00	0.001319	0.44	99.75	0.009012	3.00
70.00	0.001577	0.53	99.90	0.011603	3.87
80.00	0.001999	0.67			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000491	0.16	90.00	0.002875	0.96
20.00	0.000660	0.22	95.00	0.003809	1.27
30.00	0.000808	0.27	97.50	0.004767	1.59
40.00	0.000960	0.32	99.00	0.006201	2.07
50.00	0.001134	0.38	99.50	0.007606	2.54
60.00	0.001317	0.44	99.75	0.009009	3.00
70.00	0.001575	0.53	99.90	0.011602	3.87
80.00	0.001997	0.67			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 42 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Reference Dose (aRfD) = 0.300000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Adults 50+ yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean	0.001495	0.001495
Standard Deviation	0.001415	0.001415
Standard Error of mean	0.000015	0.000015
Percent of aRfD	0.50	0.50

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000447	0.15	90.00	0.002993	1.00
20.00	0.000613	0.20	95.00	0.004062	1.35
30.00	0.000758	0.25	97.50	0.005180	1.73
40.00	0.000909	0.30	99.00	0.007085	2.36
50.00	0.001079	0.36	99.50	0.008464	2.82
60.00	0.001292	0.43	99.75	0.010498	3.50
70.00	0.001580	0.53	99.90	0.013519	4.51
80.00	0.002048	0.68			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000446	0.15	90.00	0.002993	1.00
20.00	0.000613	0.20	95.00	0.004062	1.35
30.00	0.000757	0.25	97.50	0.005179	1.73
40.00	0.000908	0.30	99.00	0.007085	2.36
50.00	0.001079	0.36	99.50	0.008464	2.82
60.00	0.001292	0.43	99.75	0.010497	3.50
70.00	0.001579	0.53	99.90	0.013518	4.51
80.00	0.002048	0.68			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 43 of 44

U.S. Environmental Protection Agency Ver. 1.33
DEEM-FCID ACUTE Analysis for PROPICONAZOLE (1994-98 data)
Residue file: prop-tol.R98 Adjustment factor #2 NOT used.
Analysis Date: 02-02-2004/13:33:01 Residue file dated: 02-02-2004/13:18:51/8
Acute Pop Adjusted Dose (aPAD) = 0.100000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "Acute for general popn - 0.3 (0.1 is for females)"
=====

Females 13-49 yrs

Daily Exposure Analysis
(mg/kg body-weight/day)
per Capita per User

Mean 0.001437 0.001441
Standard Deviation 0.001256 0.001256
Standard Error of mean 0.000016 0.000016
Percent of aPAD 1.44 1.44

Percent of Person-Days that are User-Days = 99.74%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aPAD	Percentile	Exposure	% aPAD
10.00	0.000464	0.46	90.00	0.002831	2.83
20.00	0.000621	0.62	95.00	0.003859	3.86
30.00	0.000767	0.77	97.50	0.004792	4.79
40.00	0.000916	0.92	99.00	0.006263	6.26
50.00	0.001084	1.08	99.50	0.007633	7.63
60.00	0.001270	1.27	99.75	0.008872	8.87
70.00	0.001547	1.55	99.90	0.010794	10.79
80.00	0.001953	1.95			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aPAD

Percentile	Exposure	% aPAD	Percentile	Exposure	% aPAD
10.00	0.000459	0.46	90.00	0.002827	2.83
20.00	0.000619	0.62	95.00	0.003854	3.85
30.00	0.000765	0.77	97.50	0.004791	4.79
40.00	0.000913	0.91	99.00	0.006261	6.26
50.00	0.001082	1.08	99.50	0.007632	7.63
60.00	0.001267	1.27	99.75	0.008871	8.87
70.00	0.001545	1.54	99.90	0.010792	10.79
80.00	0.001951	1.95			

Propiconazole
PC Code:128997

Human Exposure and Risk Assessment

DP Barcode: 262299
Page: 44 of 44

ATTACHMENT 3 - Chronic Dietary Risk Assessment

U.S. Environmental Protection Agency

DEEM-FCID Chronic analysis for PROPICONAZOLE

Residue file name: C:\Documents and Settings\btomerli\My

Documents\tzoles\risk\dietary\prop\prop-tol.R98

Ver. 1.30
(1994-98 data)

Adjustment factor #2 NOT used.

Analysis Date 02-02-2004/13:21:21 Residue file dated: 02-02-2004/13:18:51/8

Reference dose (RfD, Chronic) = .1 mg/kg bw/day

COMMENT 1: Acute for general popn - 0.3 (0.1 is for females)

----- Total exposure by population subgroup -----

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.001984	2.0%
U.S. Population (spring season)	0.001976	2.0%
U.S. Population (summer season)	0.002048	2.0%
U.S. Population (autumn season)	0.001955	2.0%
U.S. Population (winter season)	0.001956	2.0%
Northeast region	0.001999	2.0%
Midwest region	0.002054	2.1%
Southern region	0.001802	1.8%
Western region	0.002185	2.2%
Hispanics	0.002353	2.4%
Non-hispanic whites	0.001930	1.9%
Non-hispanic blacks	0.001874	1.9%
Non-hisp/non-white/non-black	0.002307	2.3%
All infants (< 1 year)	0.003736	3.7%
Nursing infants	0.001779	1.8%
Non-nursing infants	0.004479	4.5%
Children 1-6 yrs	0.004922	4.9%
Children 7-12 yrs	0.002841	2.8%
Females 13-19 (not preg or nursing)	0.001554	1.6%
Females 20+ (not preg or nursing)	0.001420	1.4%
Females 13-50 yrs	0.001584	1.6%
Females 13+ (preg/not nursing)	0.001766	1.8%
Females 13+ (nursing)	0.001704	1.7%
Males 13-19 yrs	0.001895	1.9%
Males 20+ yrs	0.001544	1.5%
Seniors 55+	0.001512	1.5%
Children 1-2 yrs	0.005877	5.9%
Children 3-5 yrs	0.004615	4.6%
Children 6-12 yrs	0.003007	3.0%
Youth 13-19 yrs	0.001728	1.7%
Adults 20-49 yrs	0.001478	1.5%
Adults 50+ yrs	0.001494	1.5%
Females 13-49 yrs	0.001437	1.4%



13544

R105968

Chemical: **Propiconazole**

PC Code: **122101**

HED File Code **51200 RD Risk Reviews**

Memo Date: **04/14/2004**

File ID: **DPD296299**

Accession Number: **412-05-0094**

HED Records Reference Center
04/12/2005